REMARKS

The Final Office Action mailed on July 24, 2008 has been reviewed and the comments of the Examiner carefully considered. Claims 1-2 and 5-15 are pending. Claims 1 and 6 have been amended. Support for these amendments may be found, for example, at page 8, lines 1-3 of the specification. No new matter has been added by way of these amendments.

Rejections under 35 U.S.C. § 103

1. Claims 1-2 and 5-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kirkwood et al. (US 2004/0241214) in view of Heinecke (US 4,499,896).

Applicants respectfully disagree with this rejection. Applicants first respectfully submit that Kirkwood et al. is disqualified as prior art under 35 U.S.C. § 103(c):

> Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

As the Examiner noted, Kirkwood et al. has common inventors Breda Cullen and Derek Silcock with the instant application, and constitutes prior art under 35 U.S.C. § 102(e) based on its earlier effective U.S. filing date. However, both Kirkwood et al. and the instant application were, at the time the claimed invention was made, commonly owned by the same entity: **JOHNSON & JOHNSON MEDICAL LIMITED** with a place of business at Erskine House, 68-73 Queen Street, Edinburgh EH2 4NH (GB). Thus, Kirkwood et al. is disqualified as prior art under 35 U.S.C. § 103(c).

Further, applicants respectfully submit that Heinecke does not teach, suggest, or otherwise disclose all limitations of the instant application. For example, as the Examiner noted, "Heinecke fails to disclose a degradable material blocking the apertures, a therapeutic agent behind the degradable material and dispersed in a bioerodible substance, and a microorganism-impermeable container". Heinecke also does not disclose that the therapeutic agent is retained inside the envelope after the aperture has opened. Consequently, applicants respectfully request reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a) over

Kirkwood et al. in view of Heinecke. Further, applicants submit that claims 2 and 5-15 are thereby allowable as written as depending from an allowable independent claim.

2. Claims 1-2 and 5-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Heinecke (US 4,499,896) in view of Arnold (US 5,759,570).

Applicants respectfully disagree with this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all claim limitations. MPEP § 2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the applicant's disclosure. MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Applicants respectfully submit that the combination of Heinecke and Arnold does not teach, suggest, or otherwise disclose:

> "A wound treatment device comprising a water-impermeable envelope having one aperture, wherein the envelope contains a therapeutic agent, and wherein the one aperture in the envelope is blocked by a degradable material that breaks down in the presence of one or more components of wound fluid thereby permitting the therapeutic agent to contact the wound fluid, wherein the total area of the aperture in the envelope is from about 0.01 to about 1 cm^2, wherein the therapeutic agent is dispersed in or on a substrate larger than the total area of the aperture, and wherein the therapeutic agent is retained inside the envelope after the aperture is opened, and wherein no part of the therapeutic agent contacts the wound surface."

As discussed above, Heinecke does not teach, suggest, or otherwise disclose all limitations of the instant application, including that the therapeutic agent is retained inside the envelope after the aperture has opened wherein no part of the therapeutic agent or substrate contacts the wound surface. Arnold does not cure this deficiency.

Specifically, the Examiner failed to show, and indeed cannot show, where Arnold teaches, suggests, or otherwise discloses that "the therapeutic agent is retained inside the envelope after the aperture is opened". The Examiner merely argued that Arnold teaches that

"the therapeutic agent is retained inside the envelope after the aperture is opened *as long as exudate has not contacted the surface of the device*" (emphasis added).

Moreover, with respect to the instant invention, it is the exudate contacting the surface of the device that then opens the aperture, thereby permitting the therapeutic agent to contact the exudate while being retained inside the envelope. Claim 1 has been amended to further clarify that the therapeutic agent does not pass through an aperture to contact the wound surface after the aperture is opened and now recites that "the therapeutic agent is retained inside the envelope after the aperture is opened, and…no part of the therapeutic agent contacts the wound surface", which further distinguishes the claimed invention.

The wound contacting layer of Arnold merely absorbs wound exudate to form a bioabsorbable gel contacting the wound surface that functions as a release matrix for wound healing factors – once exudate contacts the surface of the device of Arnold, the wound healing factors are retained at the wound surface outside the envelope (*see, e.g.*, Abstract; col. 2, line 61 to col. 3, line 1; col. 4, line 60 to col. 5, line 6; col. 6, lines 61-66; and **FIG. 1**, element 5). Arnold discloses that this "layer of wound-friendly gel" containing the wound healing factors retained at the wound surface outside the envelope "prevents the wound contact part of the dressing from adhering to the wound" (*see, e.g.*, col. 4, lines 63-65),

As neither Heinecke nor Arnold discloses a wound treatment device wherein the therapeutic agent is retained inside the envelope after the aperture is opened, and wherein no part of the therapeutic agent contacts the wound surface, the combination does not suggest, much less teach, the instant invention. Consequently, applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 2 and 5-15 are thereby allowable as written as depending from an allowable independent claim.

VIA ELECTRONIC FILING

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5337 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5034) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

DEBORAH ADDISON ET AL.

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